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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/650,650 | 08/28/2003 | Thomas Maciag | 53689500203 | 7281 |
| 23973 | 7590 | 03/13/2006 | EXAMINER | |
| DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996 | | | LEE, BETTY L | |
| | | ART UNIT | PAPER NUMBER | 1647 |
| DATE MAILED: 03/13/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/650,650 | MACIAG ET AL. | |
| | Examiner Betty Lee, Ph.D. | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 January 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 17-19,21-26,29-31 and 42-44 is/are pending in the application.
 - 4a) Of the above claim(s) 25 and 30 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 17-19,21-26,29-31 and 42-44 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/28/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed January 13, 2006 is acknowledged. Applicant's election of Group I, claims 17-19, 21-24, 26, 29 and 42-44 with traverse is noted. Applicant argues that a prior art search directed to a polypeptide will uncover art pertaining to a recombinant cell comprising the polypeptide. Applicant's arguments have been fully considered but they are not deemed persuasive. The inventions are separate because the polypeptides are classified in different category from recombinant cells which are structurally different with different uses. These searches are not co-extensive and present an undue search burden on the Examiner. Furthermore, separate classification is *prima facie* evidence of a search burden. Moreover, different databases are used for text searching. The requirement is still deemed proper and is therefore made FINAL. Claims 25, 30 and 31 are withdrawn from consideration as directed to a non-elected invention. Claims 1-16, 20, 27-28, 32-41 are canceled. Claims 17-19, 21-24, 26, 29 and 42-44 are under examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19, 21, 26, 29, 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ish-Horowicz, *et al.* (US Patent 6004924).

The claimed invention is drawn to an isolated polypeptide encoded by the nucleic acid sequence comprising the sequence nucleotide 1 to nucleotide 3201 of SEQ ID NO. 2 which encompasses SEQ ID NO.17 (1-3201 nucleotides) and comprising the amino acid sequence SEQ ID NO. 1(1-1218 aa) which encompasses SEQ ID NO.18 (1-1067 aa residues of SEQ ID NO. 1). The claimed invention is also drawn to a composition comprising the isolated soluble polypeptide in a pharmaceutically acceptable carrier. The claimed invention is also drawn to a kit for affecting cell differentiation, angiogenesis and for inhibiting expression of Type I collagen comprising the soluble Jagged polypeptide.

Ish-Horowicz, *et al.* teach a polypeptide with 99.7% sequence homology to the instant application encoding an isolated nucleic acid (6464 bp) (col 87-98, SEQ ID NO. 5). Nucleotide 371-4027 (SEQ ID NO.5) corresponds to nucleotide 1-3657 of SEQ ID NO. 2 and encompasses SEQ ID NO.17 of the instant application. Ish-Horowicz, *et al.* teach an isolated polypeptide with 99.8% sequence homology to SEQ ID NO. 1 and 18 of the instant application (col 95-102, SEQ ID NO. 6) and the mismatch occurs outside of SEQ ID NO. 18. Ish-Horowicz, *et al.* teach the pharmaceutical composition comprising a therapeutically effective amount of protein or nucleic acid in a pharmaceutically acceptable carrier (col 37, lines 36-67, col 38, lines 1-63). Kits for affecting cell differentiation, angiogenesis and for inhibiting expression of Type I collagen are intended use and are anticipated by the polypeptide of Ish-Horowicz, *et al.*

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ish-Horowicz, *et al.* (US Patent 6004924) in view of Ellison, *et al.* (J. Biol. Chem. 266:21150-21157, 1991).

The claimed invention is drawn to an isolated polypeptide encoded by the nucleic acid sequence comprising the sequence nucleotide 1 to nucleotide 3201 of SEQ ID NO. 2 and a myc tag polypeptide.

As set forth supra, Ish-Horowicz, *et al.* teach an isolated nucleic acid (6464 bp) encoding a polypeptide with 99.7% sequence homology to the instant application (col 87-98, SEQ ID NO. 5). Ish-Horowicz, *et al.* do not teach the polypeptide with a myc-tag polypeptide.

Ellison, *et al.* teach the epitope-tagged ubiquitin as a useful tool for detecting ubiquitin-protein conjugates (pg 21155, col 2). Ellison, *et al.* teach construction of a 10-residue myc-tag to the polypeptide (pg 21152, col 1, Fig 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the polypeptide of Ish-Horowicz, *et al.* with a myc-tag as taught by Ellison, *et al.* The person of ordinary skill in the art would have

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been motivated to add the myc-tag to facilitate purification of tagged proteins with commercially available myc antibodies.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Lee, Ph.D. whose telephone number is (571) 272-8152. The examiner can normally be reached on M-F 9 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BLL



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER